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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0472]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Petition for Administrative Stay of Action

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by [*insert date 30 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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Petition for Administrative Stay of Action—21 CFR 10.35 (OMB Control Number 0910–0194)—Reinstatement)—Extension

The regulations in 21 CFR 10.35, issued under the authority of section 701(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(a)), set forth the format and procedures by which an interested person may file a petition for an administrative stay of action.

Respondents to this information collection are interested persons who choose to file a petition for an administrative stay of action. Such a petition must: (1) Identify the decision involved; (2) state the action requested, including the length of time for which a stay is requested; and (3) include a statement of the factual and legal grounds on which the interested person relies in seeking the stay. The information provided in the petition is used by the agency to determine whether the requested stay should be granted.

In the **Federal Register** of September 25, 2000 (65 FR 57614), the agency requested comments on the proposed collections of information. No significant comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1. — ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
10.35	13	1	13	10	130

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimate for this collection of information is based on FDA's experience with petitions for administrative stay of action over the past 3 years. Agency personnel responsible for processing the filing of petitions for administrative stays of action estimate that 13 such petitions are received by the agency annually, with each requiring approximately 10 hours of preparation time.

Dated: December 27, 2000

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Margaret M. Dotzel
Associate Commissioner for Policy.

[FR Doc. 00–????? Filed ??–??–00; 8:45 am]

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